DETAILED ACTION

This Action is in response to the RCE filed 6/28/2011. Claims 1, 6, and 26 have been amended, and no claims have been cancelled or added. Thus, claims 1-6, 8, 9, and 12-30 are currently pending in the instant application.

Response to Arguments

Applicant's arguments filed 6/28/2011 have been fully considered but they are not persuasive.

In response to applicant's arguments against the Honeycutt reference individually (pages 13-14 of the remarks), examiner notes that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, examiner again concedes that Honeycutt doesn't teach each and every limitation of the presently claimed invention, which is why the reference was combined with others as discussed previously.

In response to applicant's argument that storing nicotine and volatile acids for slow release in *inhalers* is not well known in the art, examiner again contends that such a modification to the Honeycutt device would have been obvious to one of ordinary skill in the art upon seeing the cited references. In the rejection examiner notes that Baker does not teach the claimed PMMA matrix for specific use in an inhaler but notes that Martyn teaches that technology used for transdermal delivery and inhalation therapy are interchangeable. It doesn't matter that Martyn teaches a different (non-PMMA) composition from that of Baker because Martyn was cited

merely to show that it was known at the time of the invention that the same technologies can apply to both transdermal delivery and inhalation therapy. Thus, one of ordinary skill in the art would find motivation to try other compositions of transdermal delivery applications such as those disclosed by Baker with inhaler technologies such as those disclosed by Honeycutt as suggested/evidenced by Martyn. Also, examiner again notes that piecemeal attack of the references is not persuasive when the rejection is based on a combination of references whose teaches would be obvious to combine to one of ordinary skill in the art to arrive at the instant invention.

In response to applicant's argument that the noted features of release rate and duration/speed of inhalation are not a mere design choice, examiner respectfully disagrees. The speed and duration of inhalation is entirely up to the user because the instant invention has no structure that allows creation or limiting of the inhalation rates to those ranges claimed. As noted in the rejection, the claimed speed and duration of inhalation are considered well known inhalation processes with smoking simulators. Furthermore, given that the inhalation process claimed by the instant invention is not novel and is a process that is entirely up to a user's capabilities, and that applicant provides no claimed structure that allows the claimed release rates specifically, the release rate of the compositions from the polymer matrices are then simply a matter of dimensions, saturation, resistance, etc. of the matrix material and composition, both of which were well known for slow release of nicotine as taught by Baker. Given that the claimed nicotine amount released per puff is a well known amount as appropriate in smoking simulators and dependent on various structural properties as taught by Ek, it would have been obvious to one of ordinary skill in the art to then design the polymer matrix (i.e., dimension, material) to

allow the claimed release rates for what is a well known and obvious user inhalation duration/speed to allow an effective amount of nicotine to be released without harming the user. Such a modification is a mere optimization of a rate within a well known range to yield predictable results that do not patentably distinguish an invention over the prior art. Furthermore, there is no evidence on record of any "unexpected and superior result" from the instant invention and particles sizes of 10 microns are already well known in the art for allowing particles to reach further into the airways than larger particles.

Applicant also states that Ek is silent as to how to achieve the claimed release rates. However, the instant claims are equally silent about how the rates are reached (other than how fast and long a user inhales which apparently has nothing to do with the device itself but just a user's capabilities and desire) and as discussed above, the release rates and inhalation process is considered obvious. In response to applicant's arguments that Ek is not an enabling reference because it is an inhaler fundamentally different from the claimed invention, examiner notes that the reference is cited merely to show that the claimed invention isn't producing a novel quantity of nicotine release, and that such an amount was well known in smoking simulators/inhalers at the time the invention was made. The rest of the statements on page 17 of the remarks pertaining to Ek are considered a piecemeal attack on the reference (i.e., it doesn't matter that Ek lacks the structure of the inhaler because that is found in Honeycutt).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 8, 9, and 12-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, lines 18-19, the term "the basic active agent" should be changed to --the basic active agent or nicotine base-- since there can be either one present to still read on the instant claim.

Regarding claim 8, in line 3, the limitation of the particle sizes is already claimed in claim 1 and should be deleted from claim 8.

In claim 26, line 3, "preparation" should be changed to --first preparation-- to avoid any confusion as to which preparation is being referred to here.

Claims 2-6, 9, and 12-25, and 27-30 are rejected by virtue of their dependence on claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1, 2, 5, 6, 8, 12, 14, 22, 23, 26, and 30 are rejected under 35 U.S.C. 103(a) as obvious over Honeycutt (4,765,348) in view of Baker et al. (US 5,721,257, herein referred to as "Baker"), Martyn et al. (WO 2003/053413, herein referred to as "Martyn"), and Ek et al. (US 2005/0053665, herein referred to as "Ek").

Regarding claims 1, 2, 5, 8, 12, 14, 22, 23, 26, and 30, Honeycutt discloses a device for administration of nicotine to the human body by inhalation (column 1, lines 37-45) for the purpose of being a non-combustible simulated cigarette (column 1, 8-10), wherein the device comprises a first preparation (18) containing a free base of nicotine (column 1, lines 45-46) which is contained by absorption in a polytetrafluoroethylene element (column 3, lines 11-18), and a second preparation (20) containing a volatile acid (column 1, lines 46-52), such as acetic acid (column 2, line 39) which is separated from the first preparation (18) by an impermeable partition (24) (column 2, lines 48-49). The device contains a first air inlet, located to the right of section 18 in figure 3, directing an inhaled airstream into an oblong air supply channel, around #18 in figure 3, a second air inlet, located to the right of section 20 in figure 3, directing an inhaled airstream into an oblong air supply channel, around #20 in figure 3, a common flow path (22) where the two airstreams from the separate sections combine simultaneously due to inhalation and an outlet aperture (16) where the common flow path leads to (column 2, lines 60-69), all of which have a conduit cross-section.

Honeycutt lacks the first and additional preparations comprising a polymer matrix with the agent and acid being contained in a dissolved or dispersed form. However, Baker discloses a smoking cessation device with nicotine and/or additive salts including acetic acid (column 7, lines 20-25) dispersed (column 8, lines 20-35) within a PMMA polymer matrix (column 10, lines 5-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have dispersed the nicotine and acid of Honeycutt in polymer matrices as taught by Baker in order to safely deliver a slow release of nicotine to a user for smoking cessation.

Examiner notes that Baker teaches the device for transdermal delivery. However, Martyn teaches a similar slow release composition in which therapeutic agents (including acids) are dispersed in a polymer matrix (abstract) and can be used in either transdermal or inhalation therapy (see claims 10 and 11). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the dispersed form of preparations taught by Baker for inhalation therapy in the modified Honeycutt/Baker device since at the time of the invention it was well known that such compositions and technologies were interchangeable as taught/evidenced by Martyn. Such a modification appears to involve the mere use of one well known nicotine storage/release means for another to yield predictable results that do not patentably distinguish an invention over the prior art. Furthermore, there is nothing structurally in Honeycutt preventing the preparations from being stored/released using polymer matrices as taught by Baker (or any similar well known means for that matter).

Honeycutt is also silent as to the exact flow rates and nicotine release. However, Ek discloses that during inhalation therapy, depending on flow resistance, etc. an average amount of 8-10 micrograms of nicotine is released per puff from nicotine contained within cellulose matrices (paragraph 106). Therefore, absent a critical teaching and/or showing of unexpected results from such flow rates, examiner contends that puffs from 1-10 seconds at 01-1 L/min are well known as common for smokers and that with such puffs, release of 5-250 micrograms of the nicotine would have been obvious because such amounts are common in the art at taught by Ek for delivering an effective and safe amount of nicotine to a user. The exact amount would depend on design considerations such as how much nicotine was dispersed in the matrix, the puff

strength, flow properties of the device, etc., which would depend on user capabilities and mere changes in dimension.

Likewise, Honeycutt is silent as to particle size and negative pressure differential. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device with appropriate size elements to create airflows and chemical balances necessary to operate the device successfully (column 3, lines 1-10), since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Additionally, a mere change in dimension does not patentably distinguish an invention over the prior art and particles of less than 10 microns are well known as appropriate and commonly used for allowing delivery of particles to a user's airways as taught by Martyn (see page 4, lines 5-10).

Regarding claim 6, Honeycutt discloses the chemical balance between volatized nicotine and acid can be controlled (column 3, lines 1-10), but does not disclose the exact ratio of the chemical balance. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made that during inhalation a ratio of equimolar quantities of the nicotine and acid could be released in order to provide the advantage of giving the vapor a neutral pH.

Claims 3, 4, 9, 24, 25, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt, Baker, Martyn, and Ek as applied to claims 1, 2, 5, 6, 8, 12, 14, 22, 23, 26, and 30 above, and further in view of Ray (4,284,089).

Regarding claims 3, 4, 9, 24, 25 and 27, Honeycutt does not disclose the preparations containing a solvent suitable for inhalation. However, Ray teaches a preparation containing

water as a solvent as well as menthol dissolved in ethanol as a flavoring (column 4, lines 23-28; column 7, lines 14-22). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the inhaler of Honeycutt with solvents as taught by Ray in order to provide the advantages of adjusting the humidity of vapors released and providing flavor to the vapors.

Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt, Baker, Martyn, and Ek as applied to claims 1, 2, 5, 6, 8, 12, 14, 22, 23, 26, and 30 above, and further in view of Turner (5,400,808).

Regarding claims 28 and 29, Honeycutt discloses the device having an impermeable part (24) (column 2, lines 48-49) as well as discloses that the device can be made of any material (column 2, lines 11-13), but does not disclose a definite composition of the whole device. However, Turner teaches a nicotine impermeable container constructed of aluminum foil coated with a copolymer of acrylonitrile and methyl acrylate (column 2, lines 36-41). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the inhaler of Honeycutt with a material as taught by Turner in order to provide the advantage a longer shelf life of the contents of the inhaler. In addition, having the entire device be made out of the impermeable material of impermeable partition (24) and for this material to be a polyester material coated with a copolymer would help ensure all the composition released is directed through the outlet to the airway. See also *In re Leshin*, 125 USPQ 416, ion which is was held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt, Baker, Martyn, and Ek as applied to claims 1, 2, 5, 6, 8, 12, 14, 22, 23, 26, and 30 above, and further in view of Ferre (726,037).

Regarding claim 13, Honeycutt does not disclose a peelable protective layer to form compartments containing the active agent and acid protecting them from ambient air. However, Ferre teaches an inhaler with separate impermeable (lines 53-54) compartments (a, c) that have orifices (f) that can be opened or closed (line 70). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the inhaler of Honeycutt with a sealable compartments as taught by Ferre, and for the compartments to be sealable with a peelable layer in order to provide the advantage of a longer shelf life of the contents of the compartments as well as an inexpensive, easy disposable sealing means as is well known in the art.

Claims 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt, Baker, Martyn, and Ek as applied to claims 1, 2, 5, 6, 8, 12, 14, 22, 23, 26, and 30 above, and further in view of Kallstrand (5,660,169).

Regarding claims 15-21, Honeycutt discloses the claimed structure of the invention needed to read on claims 15-21, including the oblong recesses as discussed above in the rejection of claim 1, but lacks the parts being formed by deep-drawing. Kallstrand discloses an inhaler device with an upper (1) and bottom part (2), containing a compartment with a peelable seal (figs. 3a-c), formed by deep-drawing (column 2, lines 11-14). Therefore it would have been

obvious to one of ordinary skill in the art at the time of the invention to provide the inhaler of Honeycutt with deep-drawn components as taught by Kallstrand in order to provide the advantage of an inexpensive way to manufacture the device. Furthermore, there is nothing structurally preventing the device from being manufactured using any well known technique and it appears as though the modified Honeycutt device would work equally well if produced by deep-drawing. such a modification appears to involve the mere use of a well known manufacturing means in a well known device to yield predictable results that do not patentably distinguish an invention over the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/
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